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09/330,629	06/11/1999	CLAUDIA CHERNEY STEWART	JG-RP-4796	9658

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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Application Number: 09/330,629
Filing Date: June 11, 1999
Appellant(s): STEWART, CLAUDIA CHERNEY

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EXAMINER'S ANSWER

This is in response to the appeal brief filed July 18, 2007 appealing from the Office action mailed July 6, 2006.

(1) Real Party in Interest

A statement identifying by name the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The statement of the status of claims contained in the brief is correct.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is correct.

(6) Grounds of Rejection to be Reviewed on Appeal

The appellant's statement of the grounds of rejection to be reviewed on appeal is correct.

(7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct.

(8) Evidence Relied Upon

WO93/11140	Dori	6-1993
4,242,359	Cooper et al.	12-1980

Field, Virology, pages 26-27, Lippincott-Raven,1996

Merck Manual, 16th ed., 1992, pages 49-55

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 41-53 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-12 of copending Application No. 10/662,848 (hereinafter '848) in view of Field, reference of record. Although the conflicting claims are not identical, they are not patentably distinct from each other because '868 discloses the same method of prophylaxis the transmission of viral infection to the recipient. Even though '848 does not expressly disclose the specific herein claimed dosage and regimen of the metallo-cobalt

compounds nor the prophylaxis treatment for HIV, such prophylactic treatment and adjustment of dosage and regimen would have been obvious to one of ordinary skill in the art at the time the invention was made. Field teaches HIV as one of the common pathogens to human. It would have been obvious to one of ordinary skill in the art at the time of invention to employ the compounds of '848 to inhibit the transmission of any pathogenic virus including HIV, since the compounds of '848 is known to inhibit any virus transmission. Thus, employing the compounds of '848 in the method of prophylactic treatment for any viral diseases, such as HIV, would be reasonably expected to be effective. Furthermore, optimize the dosage and regimen as recited in the instant application since the optimization of result effect parameters (dosage range, dosing regimens) is obvious as being within the skill of the artisan.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 41-53 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dori (WO93/11140) in view of Cooper et al. (US Patent 4,242,359), references of record

in the parent application and Field (Virology, page 26-27, Lippincott-Raven, 1996) and Merck Manual, 16th ed., 1992, pages 49-55.

Dori teaches the method of treating viral infection and decreasing viral titer broadly by topically administering the metallo-organic cobalt compounds, including compound No. 96 in the instant specification, with a concentration of 0.5 to 10mg/ml (0.05 to 1% by wt) (See page 13, line 16-19; page 19-27, experiment 1-7; claims 1 and 11). Dori also teaches the dosage form of the metallo-organic cobalt compounds may be ointments, salves, and creams (See page 12, lines 16-17). Dori also teaches the metallo-cobalt compounds are useful in treating viral infection broadly, especially for viruses which are well-known in the art, such as listed in Field et al., Virology (See page 11, line 19-page 12, line 4).

Dori does not expressly teach the method of prophylaxis for Human Immunodeficiency Virus (HIV) infection by topically administering the metallo-organic cobalt compound No. 96 in the instant specification to the site on the subject which is exposed to the HIV. Dori also does not expressly teach the method of using a condom as an applicator to topically apply the compound No.96.

Cooper et al. teaches a method of topical administration of a medical agent by applicators including a condom is known in the art (See abstract and col. 8, line 40-44).

Field teaches the common viral pathogens in human (See Table 4 in page 26-27).

Merck Manual teaches employing anti-infective agents (both antiviral and antibacterial) in antimicrobial chemoprophylaxis as common practice in the pharmaceutical field (See pages 49-55).

Therefore it would have been obvious for one of ordinary skill in the art at the time the invention was made to topically administer the instant compounds to the site on the subject by using a condom as an applicator for the prophylaxis of HIV infection.

One of ordinary skill in the art would have been motivated to utilize the instant compounds for the prophylaxis of HIV infection because the compounds of Dori are known to be effective in treating viral infections and decreasing viral titer, broadly. It is therefore reasonable to expect the very same compounds, including compound 96, to be useful in prophylaxis, or reduction in the incidence of, any viral infections including those caused by HIV strains since, based on Field, HIV1 and HIV2 are known to be pathogenic to human since such metallo-organic compounds can be used to reduce the number and thereby the incidence of HIV.

Furthermore, one of ordinary skill in the art would have been motivated to topically administer the instant compound by using a condom as an applicator because the method of topical administration of pharmaceutical actives by applicators on to the site that may exposed to the HIV infection, such as the vagina, including a condom is known in the art.

It is noted that appellant's acknowledgement of the provisional double-patenting rejection. Once, the instant case is found to be patentable, the appellants plan to file a terminal disclaimer to obviate the obviousness double-patenting rejection.

(10) Response to Argument

Appellant's arguments in pages 4-5 in the Brief filed July 18, 2007 averring the cited prior art's failure to teach the blocking of the viral entry by the herein claimed compounds are not convincing. The examiner notes that the features upon which appellant relies (i.e., blocking the viral entry to a cell by the herein claimed compounds) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

The instant claims merely recites a method of prophylactically reducing the risk of HIV infection. As discussed in the advisory action mailed March 1, 2007, the prophylaxis of HIV does not necessarily and only accomplished by inhibiting the viral entry to the cells. It can also be done on the basis of inhibiting the first replication of the virus once it get into the cell and thereby inhibit or reduce the chances of HIV manifestation in the patients. In the instant case, the herein claimed compounds can lower the viral titer and known to be useful in treating viral infection. Therefore, it would be reasonably expected to be useful in lowering the viral titer or killing the virus once it enters the body and thereby reduce the chance of manifestation of HIV infection. In other words, inhibiting the replication of the virus, as taught by Dori, will reduce the risk the clinical manifestation of the HIV infection, absent evidence to the contrary.

Various references are provided by the appellant in attempt to explain the mechanism of blocking the viral entry to a cell as important to the instant invention. However, as discussed above, blocking the viral entry should not be the only way to reduce the chances of infection. The fact that appellant has recognized another advantage which would flow naturally from following the suggestion of the prior art cannot be the basis for patentability when the differences would otherwise be obvious. See *Ex parte Obiaya*, 227 USPQ 58, 60 (Bd. Pat. App. & Inter. 1985).

(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

The information disclosure statements (IDS) submitted on January 8, 2007 and December 6, 2006 were filed after the mailing date of the Final Office on July 6, 2006. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Respectfully submitted,

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